

REMARKS

Applicants submit this paper in response to the office action the Office mailed on August 21, 2006.

5 The claims are amended to recite the use a single compound, 3 β ,17 β -dihydroxyandrost-5-ene in the claimed methods.

New claims 119-138 replace previously presented claims 80-94 and 106-118 (treatment of humans).

10 New claims 139-146 replace previously presented claims 95-105 (treatment of non-human primates).

Support for the term "ameliorate" in the context of treating immune suppression conditions in subjects that have or that are subject to developing such conditions is at least at paragraphs 314 and 563-564. New independent claims 119 and 139 recite specific routes of administration and clinical conditions.

15 The amendments introduce no new matter.

Interview Summary

The interview summary the Examiner provided at the end of the interview reflects the discussion the undersigned and Dr. Christopher Reading had with
20 Examiner Badio on July 13, 2006. The prior art of record, U.S. patent 5,461,042 (hereafter the '042 patent) was discussed. Patentable differences between the claims in this application and the subject matter in the '042 patent were discussed. The amended claims reflect some aspects of the interview discussions to address some of these issues. Applicants appreciate the
25 Examiner's courtesy and time in the conduct of the interview.

35 U.S.C. § 112, first paragraph

The Office rejected claims as allegedly not enabled 80-86, 88, 90-111 and 113-118 for preventing innate immune suppression due to radiation exposure.
30 Applicants have amended new independent claims 119 and 139 to replace the term 'prevent' with the term ameliorate. These amendments are made without prejudice and Applicants maintain their traverse of the rejection for reasons

discussed in prior responses. Applicants request reconsideration and withdrawal of the rejection in view of this amendment.

35 U.S.C. § 103(a)

5 The Office rejected claims 80-86, 88, 90-111 and 113-118 as allegedly obvious in view of U.S. patent No. 5,461,042 (hereafter the '042' patent). Applicants maintain their traverse the rejection to the extent it applies to the amended claims. Applicants assert that for reasons of record, the Office has not established a prima facie case of obviousness.

10 Applicants respectfully assert that the presently claimed subject matter recites dosages and dosing regimens that are outside the teaching of the '042 patent cited above, which weakens the Office's assertion of obviousness. *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994). The only express suggestion in the '042 patent to change dosages is express teaching to reduce dosages for routes of
15 administration such as subcutaneous injection (column 17, lines 37-47) below the maximum 30 mg dose specified for androst-5-ene-3 β ,17 β -diol. The '042 patent provides no motive to change its protocols or teaching to arrive at the presently claimed subject matter, which is required to establish a prima facie case of obviousness. *Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353; 52
20 U.S.P.Q.2D 1294 (Fed. Cir. 1999); M.P.E.P. §§ 2143.01(I), (III) and (IV). Based on the record, the rejection is based on impermissible hindsight. *In re Dembiczak*, 175 F.3d 994; 50 U.S.P.Q.2D 1614 (Fed. Cir. 1999).

 The references that the Office cited for the proposition that dosages and treatment regimens are routine, e.g., U.S. patent Nos. 3,818,042 or 3,818,093,
25 exemplify the Office's failure to see the hindsight basis for the rejection. 35 USC § 103(a) contains the following statement: Patentability shall not be negated by the manner in which the invention was made. The courts have expanded on this: "patent acquisition does not require any threshold level of effort or ingenuity. See 35 U.S.C. § 103(a) (2000) ("Patentability shall not be negated by the manner in
30 which the invention was made."); 35 U.S.C. § 103 Revision Notes and Legislative Reports, 1952 Notes ("It is immaterial whether [the invention] resulted from long

toil and experimentation or from a flash of genius."); *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) (stating that "the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute"). *CFMT, Inc. and CFM Technologies, Inc., v. Yeldup International Corp.*, 5 349 F.3d 1333 (Fed. Cir. 2003).

Therefore, the fact that an invention may or may not have been made using routine methods is irrelevant to patentability. The only relevant consideration here is whether the '042 patent itself fairly teaches or suggests the presently claimed subject matter. The express teaching in the '042 patent is to 10 use a 30 mg dose of androst-5-ene-3 β ,17 β -diol to treat "larger adult mammals" or a lower dose if the compound is administered by a subcutaneous, intrathecal or inhalation route (non-oral routes) of administration. The only way one arrives at the presently claimed subject matter is to get that subject matter from the pending claims themselves. Applicants respectfully assert that the Office has not 15 presented a prima facie case of obviousness and Applicants request withdrawal of the rejection.

In addition to the foregoing arguments, Applicants direct the Office's attention to the declaration by Dr. Reading that accompanies this response. The declaration presents evidence of results from practice of the claimed methods in 20 both humans and non-human primates that are unexpected and unpredictable in view of the '042 patent. As explained in the Declaration, the dosages and dose regimens needed to obtain neutrophil responses in humans and non-human primates were completely outside the scope of the teaching of the '042 patent. Results from a clinical trial in healthy patients shows that sufficient dosages of 25 androst-5-ene-3 β ,17 β -diol was capable of increasing neutrophils in the face of homeostasis mechanisms that tend to keep neutrophil levels constant. Results from dosing androst-5-ene-3 β ,17 β -diol to non-human primates after radiation exposure showed increases in neutrophils and increased survival after exposure to high levels of radiation.

In view of the foregoing comments and the evidence of unexpected results described in the Declaration, Applicants respectfully request reconsideration and withdrawal of the rejection.

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Concluding remarks

Please charge any additional fees, except the issue fee, that are due now (except the issue fee), or credit any overpayment to Deposit Account No.

501536.

Respectfully submitted,

10 Date: February 21, 2007

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